#### PATENT COOPERATION TREATY

### **PCT**

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 664240	FOR FURTHER ACTION	See item 4 below	
International application No. PCT/JP2004/000291	International filing date (day/month/year) 16 January 2004 (16.01.2004)	Priority date (day/month/year) 20 January 2003 (20.01.2003) ]	
International Patent Classification (IPC) or national classification and IPC <sup>7</sup> A61L 15/00, A61F 13/00			
Applicant JURIDICAL FOUNDATION THE CHEMO-SERO-THERAPEUTIC RESEARCH INSTITUTE			

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 <i>bis</i> .1(a).				
2.	This REPORT consists of a total of 6 sheets, including this cover sheet.				
	In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.				
3.	. This report contains indications relating to the following items:				
	Box No. I	Basis of the report			
	Box No. II	Priority			
	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability			
	Box No. IV	Lack of unity of invention			
	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement			
	Box No. VI	Certain documents cited			
	Box No. VII	Certain defects in the international application			
	Box No. VIII	Certain observations on the international application			
4.	The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).				

Date of issuance of this report 02 September 2005 (02.09.2005)

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#### PATENT COOPERATION TREATY

Translation From the INTERNATIONAL SEARCHING AUTHORITY To: PCT WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1) Date of mailing 20-04-2004 (day/month/year) Applicant's or agent's file reference FOR FURTHER ACTION 664240 See paragraph 2 below International application No. International filing date (day/month/year) Priority date (day/month/year) PCT/JP2004/000291 16-01-2004 20-01-2003 International Patent Classification (IPC) or both national classification and IPC A61L 15/00, A61F 13/00 Applicant JURIDICAL FOUNDATION THE CHEMO-SERO-THERAPEUTIC RESEARCH INSTITUTE 1. This opinion contains indications relating to the following items: Box No. I Basis of the opinion Box No. II Priority Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability Box No. IV Lack of unity of invention Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial Box No. V applicability; citations and explanations supporting such statement Box No. VI Certain documents cited Box No. VII Certain defects in the international application Box No. VIII Certain observations on the international application FURTHER ACTION If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered. If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later. For further options, see Form PCT/ISA/220. For further details, see notes to Form PCT/ISA/220. Name and mailing address of the ISA/JP Date of completion of this opinion Authorized officer Facsimile No. Telephone No.

International application No.
PCT/JP2004/000291

Bo	x No. I	Basis of the report	
1.	With	regard to the language, this opinion has been established on the basis of:	
		the international application in the language in which it was filed	
		the translation of the international application into	, which is the language of a
		translation furnished for the purposes of international search (Rule 12.3(a) and 23.1(b)).	,
2.	With inver	regard to any nucleotide and/or amino acid sequence disclosed in the international application and this opinion has been established on the basis of:	and necessary to the claimed
	a.	type of material	
		a sequence listing	
		table(s) related to the sequence listing	
	b.	format of material	
	,	on paper	
		in electronic form	
	c.	time of filing/furnishing	
		contained in the international application as filed	
		filed together with the international application in electronic form	
	Ì	furnished subsequently to this Authority for the purposes of search	
	'		
3.		In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating furnished, the required statements that the information in the subsequent or additional copies is identicated or does not go beyond the application as filed, as appropriate, were furnished.	ting thereto has been filed or al to that in the application as
4.	Addit	tional comments:	

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Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
The questions who applicable have no	ether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially theen examined in respect of:
the enti	re international application
K 7	Nos. 7-20
because:	
	international application, or said claims Nos. 7-20
relate to	the following subject matter which does not require an international search (specify):
	Refer to the Supplemental Box.
the desc are so u	ription, claims or drawings (indicate particular elements below) or said claims Nos.
	ns, or said claims Nos are so inadequately supported escription that no meaningful opinion could be formed ( <i>specify</i> ):
a meanin fur anc	ational search report has been established for said claims Nos. 7-20 gful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit: nish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, such listing was not available to the International Searching Authority in a form and manner acceptable to it. nish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative tructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
a meanin	gful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the itime limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis ministrative Instructions, and such tables were not available to the International Searching Authority in a form and
the tables requireme	related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical into provided for in Annex C-bis of the Administrative Instructions.
	emental Box for further details.

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BOX NO. V F		Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		p or industrial applicability;			
1.	Statement					· · · · · · · · · · · · · · · · · · ·	
	Novelty (	(N)	Claims	-		,	YES
			Claims	1-6,	21-34		NO
	Inventive	sten (IS)			-		
	mvemmve	step (13)	Claims			Y	YES
			Claims	1-6,	21-34	N	O
	Industrial	applicability (IA)	Claims	1-6,	21-34	Y	YES
			Claims				10
							10

2. Citations and explanations:

The inventions that are set forth in claims 1 to 6 and 21 to 34 lack novelty in the light of document 1 and document 2 cited in the international search report. Document 1 (claims 1, 6 and 9) and document 2 (claims 1 and 2) disclose hemostatic materials which comprise thrombin and a fibrinogen as active components and comprise a bioabsorbable material as a support.

Document 1: WO 00/38752 A1

Document 2: WO 02/058749 A2

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box III

Claims 7 to 20

The inventions that are set forth in claims 7 to 20 pertain to a method for the treatment of the human body by therapy, and thus relate to a subject mater for which the present International Preliminary Examining Authority is not required to carry out an international preliminary examination under the provisions of PCT Rule 67.1(iv).